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Review Article

A Review Article on the Formulation and Evaluation of Fast Dissolving Tablet of Naproxen

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Abstract

Fast dissolving tablets are the most vital form of solid dosage form which are administered orally in the absence of water or fluid intake. Such tablets when put on the tongue, it readily dissolve or disintegrate in the saliva without chewing or water within <60 seconds and it improves the efficacy of APIs. In this study, the main objective was the Formulation & Evaluation of the given drug (Naproxen) & testing its various parameters such as weight variation, hardness, thickness, friability, drug content, Angle of Repose, Carr's Index along with the disintegration studies and Drug Excipient compatibility and the results were found to be within the limits. Here, the Direct Compression technique was used to formulate the batch of Tablets (250 mg).

Keywords: Naproxen; Fast Dissolving; Disintegration; Direct Compression

Introduction

Fast disintegrating tablets have better patient compliance and may offer improved biopharmaceutical properties, improved efficacy and better safety compared with conventional oral dosage forms. Today, fast disintegrating tablets are more widely available as over-the counter products for the treatment of allergies, cold and flu symptoms. The target population has expanded to those who want convenient dosing anywhere, anytime, without water [1]. The future potential for these products is promising because of the availability of new technologies combined with strong market acceptance and patient demand. Future possibilities for improvements in Rapid disintegrating and drug delivery are bright, but the technology is still relatively new. Several drug delivery technologies that can be leveraged on improving drug therapy from these dosage form [2-10].

Materials and Methods

The Fast dissolving tablets in this study were prepared by direct compression method. The powder mixture containing drug and other excipients were weighed and thoroughly blended in morter and pestle and then directly compressed using rotary punching machine. The compression force was adjusted to obtain tablets and weighted up to 250 mg.

SL no.	Chemical's used	F1 (mg)
1	Naproxen	150
2	MCC	18
3	Mannitol	26
4	CCS	40
5	Aspartame	10
6	Magnesium stearate	6
	Total	250

Table 1: Composition of drug and excipient.

Pre-formulation studies

Preparation of mixed blend of drug and excipients:

Required quantity of each ingredient was taken for each specified formulation and all the ingredients were cogrind in a morter and pestle. The powder blend was evaluated for flow properties such as Bulk density, Tapped density, Compressibility index, Hausner ratio, Solubility studies, FTIR studies.

Evaluation of naproxen fast dissolving tablets

The formulated tablets has been evaluated for the following parameters such as Thickness, Weight variation test, Hardness test, Friability test, Appearance, Drug content uniformity, Disintegration test.

Results and Discussion

Surface morphology

Morphological characteristics such as colour, form, taste etc of naproxen were studied and the results are tabulated in table. As the API is bitter in taste, taste masking with sweetener may prove beneficial for a palatable dosage form.

Test	Specifications	Results
Descriptions		Complies
Colour	White	
Odour	None	
Form	Crystalline	
Taste	Bitter	
Solubility	Soluble in methanol and ethanol	Complies
Identification: IR-Spectrum	IR-Spectrum of the test sample should match With the IR-Spectrum of the working standard.	Complies
Assay	99% w/w	99.0% to 101.0% w/w

Table 2: Identity parameters of API.

All the Identity parameters of the API are found to be within the limits.

Physical parameters

The pure drug showed angle of repose value is 40° indicates the moderate flow properties. The compressibility index, Hausners ratio values of the drug are 23% and 1.30 indicates that the drug has fair passable compressibility properties.

Parameters	Result
Bulk density	0.51gm/cm^3
Tapped density	0.66gm/cm^3
Compressibility Index	23%
Hausner Ratio	1.30
Angle of repose	40°

Table 3: Physical parameters of API in pre-formulation studies.

Drug - Excipient compatibility studies

Fourier transforms infra-red spectroscopy (FTIR)

Naproxen

Figure 1

Wave no. (cm^{-1})	Functional group
1681.95	C-H
1718.96	C=O
1388.16	C-H
1454.41	N-H
893.11	C=C
816.74	C=C
791.01	C=C
669.46	C=C

Table 4: Identification of functional group by the wave no. of naproxen.

Naproxen + Aspartame

Wave no.(cm^{-1})	Functional Group
1722.33	C=O
1682.76	C-H
1664.84	C-H
1387.78	O-H
893.11	C=C
816.31	C=C
790.87	C=C
697.54	C=C
669.18	C=C

Table 5: Identification of function group by the wave no. of naproxen and aspartame.

Figure 2

Naproxen + CCS

Figure 3

Wave no. (cm^{-1})	Functional Group
1711.75	C=O
1684.12	C=O
1388.54	O-H
893.14	C=C
791.00	C=C
668.89	C=C

Table 6: Identification of functional group by the wave no. of naproxen and CCS.

Naproxen+Mannitol

Figure 4

Wave no.(cm^{-1})	Functional Group
1722.48	C=O
1685.27	C=O
1600.22	C=C
1417.93	O-H
1389.42	C-H
961.70	C=C
816.18	C=C
695.00	C=C
668.30	C=C

Table 7: Identification of functional group by the wave no. of naproxen and mannitol.

Parameters	Weight (mg)	Thickness (mm)	Hardness (kg/cm)	Disintegration Rate (min)	Friability(%)
F1	250	4	3.6	2	0.4

Table 8: Physical evaluation of naproxen tablets.

Standard curve of naproxen

Figure 5

Figure 6 : Prepared tablets of Naproxen by direct compression method.

Conclusion

Fast dissolving tablets of Naproxen can be successfully prepared by direct compression techniques for the better patient compliance and effective therapy. The formulated tablets were tested for the parameters such as weight variation, hardness, thickness, friability and drug content and were found to be within the limits. All the tablets passed weight variation test as the average percentage weight variation was within ±5% i.e. in the pharmacopoeia limits. The thickness was almost uniform in all the formulations and values ranged from 3mm to 4 mm. Drug content was in the range between 95 to 105%. After observing all the evaluation parameters formulations F1 was found to be best formulation which contains 150 mg Naproxen, 18 mg MCC, 26 mg Mannitol, 40 mg CCS, 10 mg Aspartame, 6 mg Magnesium stearate. Drug content was found to be 98%. Hardness and % friability was found to be 3.6kg/cm^2 and 0.4%. This results almost satisfies all the criteria as Fast dissolving tablet.

Thus, from the above study we can conclude that the formulation of the drug(Naproxen) with the respective excipients (used in this study) can be used to developed as a Fast Dissolving Tablets for the betterment of Patient Compliance.

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